

Remarks

Reconsideration and withdrawal of the rejections set forth in the Office Action dated January 31, 2007 are respectfully requested. A separate petition for a one-month extension of time accompanies this amendment.

I. Amendments

Claim 1 is amended to remove the phrase "of a post-natal subject."

Claims 2-4, 36-38, and 40 are amended to refer to "an animal" rather than a "transgenic" animal. Basis is on, for example, in Example 2, page 21, lines 1-14.

Claims 16, 39, and 43 are cancelled.

Claim 38 is amended to correct the typographical error in reciting "combinant" instead of "recombinant".

Claim 40 is amended to include the recitation that "said cassette further includes an untranslated region located 3' to the coding region and the intron, the untranslated region consisting of SEQ ID NO:7". Basis is found, for example, on page 18, lines 26-28; Fig. 2A, and Fig. 5.

Claims 41-42 are amended to depend from claim 40, rather than claim 24.

II. Objections to the Claims

Claims 38 and 42 were objected to for the informality of containing "combinant". Claim 38 is amended to replace "combinant" with "recombinant", per the Examiner's suggestion. In claim 42, this phrase is removed as it is redundant in view of the amendment to claim 42 to depend from claim 40, rather than claim 24.

Claim 39 was objected to as a substantial duplicate of allowed claim 15. Claim 39 is cancelled, per the Examiner's suggestion.

III. Rejections Under 35 U.S.C. § 112, second paragraph

Claims 1-4, 24, and 40-43 were rejected under 35 U.S.C. §112, first paragraph as allegedly failing to comply with the written description requirement. Three separate rejections were made, one with respect to claims 1-4, another with respect to claim 24, and another with respect to claims 40-43. Each is addressed individually.

Claims 1-4 were rejected as allegedly containing new matter due to the addition of reference to a "post-natal" subject. Claim 1 is amended to remove this phrase.

Claim 24 was rejected as allegedly containing new matter due to addition of a reference to SEQ ID NO:8. It is the Examiner's position that the specification as filed has basis only for vectors comprising four copies of SEQ ID NO:8, and that there "appears to be no support for cassettes comprising a hepatic locus control element comprising an enhancer consisting of SEQ ID NO:8, wherein SEQ ID NO:8 is present in more or less than four copies" (Office action dated January 31, 2007, page 3). In response, Applicants direct the Examiner to the cassettes identified in Fig. 2A is "LX/ApoEHCR-hAATp-hFIX-bpA" and "LX/ApoEHCR-hAATp-hFIXmg-bpA" and to the cassette in Fig. 2B identified as "pBS-ApoEHCR(s)-hAATp-hFIXmg-bpA". In these cassettes, the hepatic locus control element, ApoEHCR and ApoEHCR(s), contains one copy of the enhancer sequence SEQ ID NO:8. The ApoEHCR and ApoEHCR(s) sequences are identified as SEQ ID NO:4 and SEQ ID NO:9 (see page 4, lines 8-10). For the Examiner's convenience, Applicants attach a copy of Figs. 2A-2B with the identified constructs highlighted and additionally attach a copy of the sequence listing showing SEQ ID NOs: 4, 8, and 9, with the enhancer sequence SEQ ID NO:8 region of SEQ ID NOs: 4 and 9 highlighted. In view of this support for claim 24, reconsideration and withdrawal of the rejection is respectfully requested.

With respect to the rejection of claims 40-42, it was alleged that the claims were incomplete for missing an essential element, namely the untranslated region (SEQ ID NO:7). Applicants have amended claim 40 to include the untranslated region, and have amended claims 41-42 to depend from claim 40.

Based on amendments and remarks, Applicants respectfully request withdrawal of the rejections under 35 U.S.C. §112, second paragraph.

#### IV. Double Patenting Rejection

The examiner alleged that claim 16 is a substantial duplicate of claim 1 and that claim 43 is a substantial duplicate of claim 24. By this amendment claims 16 and 43 stand canceled, without prejudice.

## V. Rejections Under 35 U.S.C. § 103

Claims 1-4 and 16 stand rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Snyder *et al.* (U.S. Patent No. 6,936,243; "Snyder") as evidenced by Simonet *et al.* (*J. Clin. Invest.*, 94:1310-1319 (1994); "Simonet") and Nguyen *et al.* (*Oncogene*, 12:2109-2119 (1996); "Nguyen"), in view of Jallat *et al.* (*The EMBO Journal*, 9(10):3295-3301 (1990); "Jallat") and Kurachi *et al.* (*J. Biol. Chem.*, 270(10):5276 (1995); "Kurachi").

It is the Examiner's position that Snyder (as evidenced by Simonet and Nguyen) discloses all of the elements of the claimed invention except for the use of a Factor IX intron in the expression cassette. Jallat and Kurachi are cited for teaching that Intron I, or a fragment of Intron I, can increase the expression of Factor IX.

### Removal of the Snyder Document

In Applicants' prior response, a Declaration of Dr. Mark Kay ("Kay Declaration") was submitted in an attempt to remove Snyder as a prior art reference. However, the Examiner maintains that Snyder is prior art under 35 U.S.C. § 102(e) on the grounds that "even if the inventorship of Snyder *et al* all [sic] is considered to be only Dr. Kay, due to Carol Miao also being listed as an inventor of the instant invention" the instant inventorship is still 'by another'; and thus, "Snyder *et al* is still an invention by another" (Office action dated January 31, 2007, page 6).

In a telephone conversation, the Examiner clarified that knowledge regarding Carol Miao's contribution to the instant case would help in the determination of whether the instant inventorship is still "by another" with respect to Snyder. Applicants provide that additional information by way of a Declaration Carol H. Miao and Mark A. Kay ("the Miao-Kay Declaration"), attached. As stated in the Miao-Kay Declaration, elements of the claimed expression cassette that were not previously invented and disclosed by Dr. Kay are either joint contributions of Miao and Kay together, or were individually contributed by one of Miao or Kay. For example, Dr. Miao and Dr. Kay together conceived of adding the hepatic locus control element to the expression cassette (§ 5 of the Miao-Kay Declaration). Dr. Miao and Dr. Kay together discovered that the claimed expression cassette provided long term expression when administered *in vivo*. (§ 7 of the Miao-Kay Declaration).

The Applicants note, however, that the law does not require evidence regarding Dr.

Miao's contribution to the instant case. "When subject matter, disclosed by not claimed in a patent application issued jointly to S and another, is claimed in a later application filed by S, the joint patent is a valid reference available as prior art under 35 U.S.C 102(a), (e), or (f) unless overcome by.....an unequivocal declaration by S under 37 C.F.R. 1.132 that he or she conceived or invented the subject matter disclosed in the patent." M.P.E.P. § 716.10.

In the previously submitted Kay Declaration, Dr. Kay made an unequivocal declaration that he is the inventor of the expression cassette disclosed in Snyder. Thus, the Kay Declaration fulfills the legal requirements for removal of Snyder.

Moreover, Applicants note that Dr. Miao is not a named inventor on the Snyder patent, therefore she did not contribute to the invention in Snyder, and therefore did not invent the expression cassette disclosed in Snyder. Thus, it is axiomatic that the subject matter in the instant claims related to the expression cassette disclosed in Snyder is, at a minimum, Dr. Kay's contribution to the instant case. According to the court in *In re Katz* (687 F.2d 459, 214 USPQ 933 (CCAP 1982):

It may not be readily apparent from the statutory language that a printed publication cannot stand as a reference under § 102(a)<sup>1</sup> unless it is describing the work of another. A literal reading might appear to make a prior patent or printed publication "prior art" even though the disclosure is that of the applicant's own work. However, such an interpretation of this section of the statute would negate the one year period afforded under § 102(b) during which an inventor is allowed to perfect, develop and apply for a patent on his invention and publish descriptions if he wishes. Thus, one's own work is not prior art under § 102(a) even though it has been disclosed to the public in a matter or form which otherwise would fall under § 102(a). .....*"But certainly one's own invention, whatever the form of disclosure to the public, may not be prior art against oneself, absent a statutory bar (emphasis in original).*

Thus, it is quite clear from the law, that Dr. Kay's own work which is disclosed in

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<sup>1</sup>Although the court in *Katz* refers to § 102(a), it is established (see, for example, M.P.E.P. §§ 715.01(a), 716.10) that the holding of *Katz* applies equally to § 102(e).

Snyder may not be prior art against Dr. Kay, absent it being a statutory bar.

As further evidence that the Kay Declaration, with or without the Miao-Kay Declaration, is sufficient to remove Snyder as prior art, Applicants enclose a decision by the Board of Patent Appeals and Interferences in a case with a similar fact pattern, *Ex parte Pokora and Johnson* (Appeal No. 95-2444). Applicants Pokora and Johnson's claims were rejected as being obvious over a prior art reference to Johnson *et al.* The Johnson *et al.* reference was a patent (U.S. Patent No. 5,147,793) naming Johnson, Pokora and Cyrus as inventors. The Johnson *et al.* reference was available as prior art under 35 U.S.C. § 102(e). To remove Johnson *et al.* as a prior art reference, inventors Pokoru and Johnson submitted a declaration stating that Pokoru and Johnson were joint inventors of the subject matter in Johnson *et al.* that was related to the invention claimed in the application naming Pokora and Johnson<sup>2</sup>.

In finding that the declaration was sufficient to remove Johnson *et al.* as a § 102(e) prior art reference, the court cited to the M.P.E.P. § 716.10: "When subject matter, disclosed but not claimed in a patent application issued jointly to S and another, is claimed in a later application filed by S, the joint patent is a valid reference available as prior art under 35 U.S.C. § 102(a), (e), or (f) unless overcome by...an unequivocal declaration by S under 37 C.F.R. § 1.132 that he or she conceived or invented the subject matter disclosed in the patent".

Notably, the declaration by Pokoru and Johnson, which stated that the invention in Johnson *et al.* was attributable to Pokoru and Johnson, did not achieve a strict identity between the inventors named in Johnson *et al.* and the pending application to Pokoru and Johnson. Namely, after attribution of the subject matter in Johnson *et al.* to Pokoru and Johnson, there was not identity between the inventive entities in the prior art document and the pending application, due to the presence of Cyrus as an inventor on the prior art Johnson *et al.* document. This is evidence that the Examiner's position in

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<sup>2</sup>The Pokoru and Johnson Declaration was also signed by Cyrus, a named inventor on the prior art Johnson *et al.* document. A declaration by the co-inventors on the cited prior art document is not required, as set forth in M.P.E.P. § 715.01(a).

the instant case, that attribution of the expression cassette described in Snyder to Dr. Kay does not remove Snyder as prior art because the instant inventorship of Miao and Kay is still by "another", is not sound.

Accordingly, Applicants respectfully request reconsideration of the Examiner's decision that the Kay Declaration fails to remove Snyder as a prior art document.

Analysis of the Rejection Assuming Removal

For the reasons given above, Applicants submit that Snyder is not an effective prior art document against the instant claims. In the absence of Snyder the cited secondary references fail to establish a prima facie case of obviousness, and withdrawal of the rejection under 35 U.S.C. § 103(a) is respectfully requested.

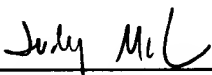
VI. Conclusion

In view of the foregoing, a Notice of Allowance is respectfully requested. If the examiner has any questions or believes a telephone conference would expedite prosecution of this application, the examiner is encouraged to call the undersigned at (650) 838-4302.

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Respectfully submitted,  
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